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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : KISHORE R. SHAH  
Serial No. : 10/748,625  
Filed : December 27, 2003  
For : BIOADHESIVE HYDROPHILIC COMPOSITION FOR  
TREATING OF MAMMALIAN SKIN  
Art Unit : 1618  
Examiner : James William Rogers  
Customer No. : 010037  
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

DECLARATION

I, Kishore R. Shah, hereby declare and say:

1. I am the named inventor in the above-identified U.S. utility patent application ("Application") and, as such, I am familiar with this Application and the facts and circumstances of its filing and prosecution.

2. I am also the named inventor and patentee in the U.S. Patent No. 5,942,243 ("243 patent") which has been cited as prior art in this Application.

*WRS*  
*5-24-2007*

3. I have also read and understood the U.S. Patent No. 6,106,820 to Morrissey ("820 patent") which was cited as prior art in this Application.

4. I have also read and understood the Office Action issued March 1, 2007 in this Application.

5. I make this Declaration in response to a request by the Patent Examiner in this Application, James W. Rogers, Ph.D., during a telephone conference with him and my attorney, Karl F. Milde, Jr., conducted on May 8, 2007.

6. I have personally conducted experiments to produce the graft copolymer compositions disclosed and claimed in the '243 patent, which copolymers comprise a hydrophilic main chain and hydrophobic graft chains consisting essentially of polystyrene. These graft copolymer compositions were mucoadhesive and were uniquely suitable for the controlled release of biologically active agents to animal tissues.

*VJR*  
5-24-2007

7. By experiment I found that all of the compositions disclosed in the '243 patent form water-insoluble, non-homogeneous fragmented hydrogels when placed in water. Each particle of the graft copolymer becomes one swollen gel without dissolving into water. This behaviour is very similar to that of crosslinked hydrophilic polymers [e.g. crosslinked poly(N-vinyl 2-pyrrolidone) or crosslinked poly(2-hydroxyethyl methacrylate)]. Typically, such fragmented gels cannot be mechanically homogenized to form a homogeneous solution-like composition. Homogenization of the said crosslinked polymers only results in smaller size of the gel fragments.

8. Subsequent to the filing date of the '243 patent, I discovered unexpectedly that upon homogenization with a laboratory blender, or by means of a Silverson type homogenizer, the hydrogels (mixture of fragmented gels), formed with the compositions disclosed and claimed in the '243 patent produced a very stable and homogeneous dispersion, which was almost solution-like in appearance and had a slight bluish haze (photo exhibit attached). When this dispersion was applied to a skin surface and allowed to

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dry, it formed a water-insoluble bioadherent film. These homogenous solution-like compositions, which form water-insoluble bioadherent films on skin, have great utility as vehicles for topical formulations for use in the treatment of mammalian skin.

9. Compositions disclosed and claimed in the '820 patent must necessarily have significantly different physical properties than the compositions disclosed and claimed in the '243 patent due to their difference in molecular structure. All of the compositions disclosed in the '820 patent have hydrophilic side chains, whereas the graft copolymers disclosed in the '243 patent have graft chains consisting essentially of polystyrene, which is hydrophobic.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of

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Title 18 of the United States Code, and that such willful  
false statements may jeopardize the validity of the patent.

5-24-2007

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Date

K.R. Shah

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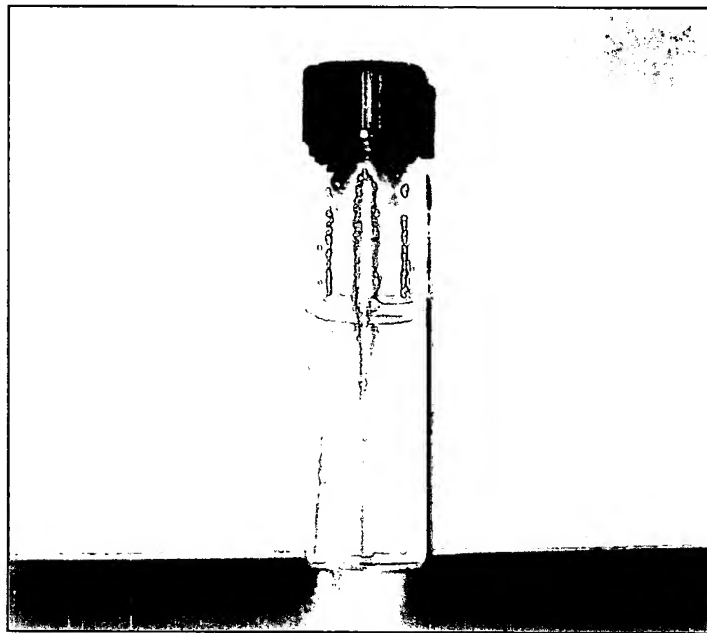
Kishore R. Shah, Ph.D.

## PHOTO EXHIBIT

### AQUEOUS DISPERSION OF GRAFT COPOLYMER

#### COMPOSITION:

Homogeneous dispersion of 5 % Poly(N,N-dimethylacrylamide-co-acrylic acid-co-polystyrene ethyl methacrylate) in water.



*KR Shah*

*5-24-2007*